

Subpart D—Extralabel Use of Human and Animal Drugs in Animals Not Intended for Human Consumption

§ 530.30 Extralabel drug use in nonfood animals.

(a) Because extralabel use of animal and human drugs in nonfood-producing animals does not ordinarily pose a threat to the public health, extralabel use of animal and human drugs is permitted in nonfood-producing animal practice except when the public health is threatened. In addition, the provisions of § 530.20(a)(1) will apply to the use of an approved animal drug.

(b) If FDA determines that an extralabel drug use in animals not intended for human consumption presents a risk to the public health, the agency may publish in the FEDERAL REGISTER a notice prohibiting such use following the procedures in § 530.25. The prohibited extralabel drug use will be codified in § 530.41.

Subpart E—Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals

§ 530.40 Safe levels and availability of analytical methods.

(a) In accordance with § 530.22, the following safe levels for extralabel use of an approved animal drug or human drug have been established: [Reserved]

(b) In accordance with § 530.22, the following analytical methods have been accepted by FDA: [Reserved]

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

- (1) Chloramphenicol;
- (2) Clenbuterol;
- (3) Diethylstilbestrol (DES);
- (4) Dimetridazole;
- (5) Iprnidazole;
- (6) Other nitroimidazoles;
- (7) Furazolidone.
- (8) Nitrofurazone.

(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);

(10) Fluoroquinolones; and

(11) Glycopeptides.

(12) Phenylbutazone in female dairy cattle 20 months of age or older.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved]

(c) [Reserved]

(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

(1) Adamantanes.

(2) Neuraminidase inhibitors.

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002; 68 FR 9530, Feb. 28, 2003; 68 FR 14134, Mar. 24, 2003; 71 FR 14377, Mar. 22, 2006]

EFFECTIVE DATE NOTE: At 77 FR 745, Jan. 6, 2012, § 530.41 was amended by adding paragraph (a)(13), effective April 5, 2012. For the convenience of the user, the added text is set forth as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) * * *

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(13) Cephalosporins (not including cephapirin) in cattle, swine, chickens, or turkeys:

(i) For disease prevention purposes;

(ii) At unapproved doses, frequencies, durations, or routes of administration; or

(iii) If the drug is not approved for that species and production class.

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PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

Subpart A—General Provisions

Sec.

556.1 General considerations; tolerances for residues of new animal drugs in food.